

REMARKS

Claims 36-41 and 44-76 were pending prior to this amendment. In this paper, claim 36 has been amended, claim 73 has been cancelled, and new claim 77 has been added. Claims 36-41, 44-72, 74-77 are currently pending.

We have addressed the points raised in the Office Action of October 20, 2008 as follows:

1. Amended Claim 36 Complies with 35 USC §112

Claim 36 has been amended to add the phrase “said capsule” as suggested by the Examiner. As amended, the Examiner’s concerns are believed to be fully addressed, and withdrawal of the objection is therefore warranted.

2. Cancellation of Claim 73 Obviates Rejection under 35 USC §112

Claim 73 has been cancelled thus rendering the rejection under §112 moot.

3. Claims 36-41, 44-72 And 74-77 Are Non-Obvious over the Teachings of Theobald and Dorment

Applicant respectfully disagrees with the Examiner’s position that Theobald *et al.* renders claims 36-41 and 74-76 obvious. The analysis under Graham would not suggest that the invention as described in the claims is obvious.

Theobald:

Theobald describes a dry powder inhalation device, referred to as a nebulizer. The nebulizer body has two main cavities, a powder chamber (5) and a bore (3) which are connected via an inlet port (6), which allows powder to pass from the powder chamber and into the bore.

The powder chamber (5) has an access opening that allows a powder dose to be loaded into the device. A screw-on valve assembly (7) seals this powder chamber. The valve assembly has a hollow probe (8) through which air may be drawn into the chamber. Significantly, the valve assembly is equipped with a one-way valve that allows air to enter the chamber through the valve assembly but prevents airflow in the opposite direction.

A piston (4) is positioned in the bore, where it is axially slid able. The piston has a piston head (12) at one end and a spike (10) at the other. The piston is axially movable to allow the spiked end to extend through the inlet port (6) and partially into the powder chamber. The spiked end is intended to rupture a capsule containing a powder as discussed below.

The bore is equipped with an outlet port (15), which permits passage of aerosolized powder out of the nebulizer.

The nebulizer is loaded by placing a dose of powder into the powder chamber and then screwing the valve assembly (7) into place. The dose of powder may be pre-metered and contained in a sealed gelatin capsule or blister or in other suitable form. When a capsule is used, the hollow probe of the valve assembly pierces the end of the capsule when the valve assembly is screwed on.

Prior to being actuated, the spike resides outside the powder chamber and is maintained in this position by a spring. To activate the nebulizer, a user applies pressure to the piston head, compressing the spring, and driving the spike (10) to be driven through the inlet port (6) and into the powder chamber, where the spike pierces the side of the capsule (in the primary embodiment described), thus creating an exit for the contents of the capsule.

The return stroke of the piston, being biased by the spring, causes air to be drawn through the one-way valve, thereby entraining the powder in the powder chamber causing it to flow from the rupture in the capsule through the inlet port and into the bore.

A further compression of the piston head causes the mass of powder contained in the bore to be turbulently ejected through the outlet port in the form of a plume. This plume may be inhaled or otherwise subsequently handled.

Theobald thus teaches aerosolizing a powder composition from a powder chamber. There is nothing in Theobald to suggest *reversibility* of this process thus allowing Theobald to act as a powder metering method. Theobald's use of a *one-way valve to preclude backflow through the device* is a specific teaching in the opposite direction of using a reverse flow as suggested by the Examiner.

Dorment:

US Patent No. 1,410,556 to Dorment teaches a device for administering "volatile oils" (col. 1, lines 16) such as menthol (col. 2, line 78-81). The volatile medicament in Dorment is molded or is absorbed into a substantially cylindrical material (5) which lines the interior of this device, and which prevents the material from undesirably seeping out of the device.

In contrast to these references, claim 36 recites:

A method of *providing a capsule filled with a powder* having the steps of:

(a) providing a capsule for a powder, said capsule having a body which is provided with an internal chamber to hold the powder, and first and second openings to an exterior environment, the body adapted to be displaced from a filling state, in which the first and second openings are placed in fluid communication with one another through the internal chamber thereby enabling creation of an airflow through the body from the second opening to the first opening which is able to entrain powder in the exterior environment into the internal chamber for filling thereof, to a sealing state in which the internal chamber is sealed from the exterior environment so as to retain the powder held therein,

wherein said capsule is in its filling state,

(b) creating an airflow through the body of the capsule in a direction from the second opening to the first opening to cause powder from a powder source disposed externally of the capsule to be entrained into the internal chamber of the body, and

(c) moving the capsule to its sealing state.

Thus, from the above it is apparent that Theobald teaches using a *one-way valve* in the valve assembly *to preclude airflow through the device in reverse direction*. Theobald does not suggest a reversal of this process—e.g., using a vacuum to draw materials into the powder chamber, and in fact, it specifically precludes this process by inclusion of the one-way valve. Thus, it would not have been obvious to one of ordinary skill in the art, at the time our claimed invention was made, to reverse the operation of the device of Theobald to **fill a capsule** as claimed in claim 36, let alone the claims dependent thereon.

In addition, a person of ordinary skill in the art would not think to reverse the piercing device of Theobald, as the nebuliser (1) is unsuited for creating a **capsule** that is **filled** with a powder. Specifically, Theobald relies on a predetermined clearance between the outer diameter of the piston (4) and the inner diameter of the bore (3) to function, as described on page 5, line 11-13. Upon a compression stroke of the piston (4), the powder that has transferred from the powder chamber (5) into the bore (3) is entrained with air in the bore, and is forced at high speed through the radial clearance between the piston and the bore (3), as described on page 6, line 7-10.

Thus in Theobald, it is essential that air and powder can flow through the predetermined clearance, between the piston and bore, in order for the nebuliser to function. In consequence, the powder chamber (5) of Theobald is always open to the external environment via the predetermined clearance between piston and bore. The nebuliser (1) is thus incapable of forming a capsule (sealed container) as any powder contained in the chamber would be exposed to external contaminants, and liable to escape from device via outlet port (15).

Theobald avoids these problems by the provision of a capsule (9) in which the powder is stored. Once inserted in the nebuliser, this capsule is pierced by hollow probe (8) and spike (10) and is not capable of being moved to a sealing state thereafter.

Theobald teaches alternatives to the capsule but none that are suited for storing powder within the nebuliser. Theobald teaches away from such an idea by stating that the powder may be inserted into the device as loose powder, delivered by the intermediary of other suitable packaging means (page 9, lines 19-27).

In the unlikely event that the skilled person were motivated to modify the nebuliser (1) of Theobald to provide a capsule filled with a powder, any arising device would not be able to carry out the subject matter of the instant claims. This is because adaptation of Theobald to form a capsule useful for storing powder would require sealing the device. However, sealing the clearance between piston and bore would make “placing the first and second openings in flow communication with one another through the internal chamber” (as per our claimed invention) impossible.

For the reasons set out above, our claimed subject matter is not an obvious reversal of the nebuliser of Theobald. Moreover, it is not possible to reverse the device of Theobald to arrive at our claimed invention.

Concerning the Dorment device, it is not described for use as a dry powder inhaler. Moreover, as a dry powder could not be molded or absorbed into the substantially cylindrical material (5) of Dorment and still be a “powder”, the device is unsuitable for such use if it were employed as described in the patent.

There is nothing in Dorment to suggest it could be filled by action of a vacuum, that anything other than a volatile oil, such as menthol, could be administered by the device, or that filling of the device could be accomplished except by adsorbing the volatile material to a cavity liner, or forming that liner itself out of the volatile material.

Hence, claim 36 meets the requirements of non-obviousness and therefore patentability over the teachings of Theobald and/or Dorment. By their dependency upon claim 36, claims 37-41, 44-72, and 74-77 are also patentable.

CONCLUSION

For the above-mentioned reasons, claim 36 is patentable over the teachings of the Theobald and Dorment references. Claims 37-41, 44-72 and 74-77 are patentable for the same reasons. The Applicant reserves all rights to argue for the separate patentability of any of the claims in any future proceeding.

As all points raised by the Examiner precluding allowance have been addressed herein, Applicant hereby requests reconsideration of the application, allowance of the claims, and issuance of a Notice of Allowance.

The Commissioner is hereby authorized to charge any fees required or credit any overpayment to Deposit Account No. 07-1392.

Favorable consideration of the application is hereby requested. If any minor matters exist precluding allowance of this application, the Examiner is requested to contact the Applicant's representative at the number below.

Respectfully submitted,

/James P. Riek/

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